

REMARKS

Claims 1, 3, 5-7, and 9-13 are pending. Claims 1, 3, 5 and 9-13 are rejected and claims 6 and 7 are withdrawn from consideration.

Applicants submit that no new matter has been added by way of the present amendments. For instance, the recitation of "recombinant wild-type SEB" has been replaced with "recombinant natural type SEB" in claim 1. Also, the language "a position corresponding to" has been removed from each of claims 1, 3, 5 and 9. Language relating to "derivatives" of certain amino acids has been removed from claims 1, 5 and 9. At several locations, for instance, in claims 1, 3, 5 and 9, the word "the" has been inserted prior to "natural type SEB." The dependency of claim 13 has been modified to avoid improper dependency upon a cancelled claim. Lastly, a period has been added to the end of claim 1. Accordingly, no new matter has been added.

Applicants further submit that no new issues have been raised by way of the present amendment. For instance, Applicants have simply amended the claims to adopt language suggested by the Examiner. This serves to reduce the number of issues, not raise issues that would require additional search and/or consideration.

In the event the present submission does not place the application into condition for allowance, entry thereof is requested as placing the application into better form for appeal.

In view of the following remarks, Applicants respectfully

request that the Examiner withdraw all rejections and allow the currently pending claims.

Objection to Claim 1

The Examiner points out that claim 1 lacks a period at the end. This has been addressed by the present amendment. Reconsideration and withdrawal of this objection are requested.

Issues Under 35 U.S.C. § 112, First Paragraph

The Examiner has rejected claims 1, 3, 5 and 9-13 under 35 U.S.C. § 112, first paragraph, for the reasons recited at pages 5-7 of the outstanding Office Action. Applicants respectfully traverse these rejections.

First, the Examiner has rejected the recitation of "derivatives thereof" in the present claims. Applicants submit that the term "derivatives" refers to a derivative of the substituted amino acid and not to a derivative of the entire SEB. Regardless, Applicants have amended the claims to remove this language. Reconsideration and withdrawal of this rejection are requested.

Second, the Examiner has rejected the language "a position corresponding to" in claims 1, 3, 5 and 9. This language was added in order to reflect the fact that it was not the natural type SEB being claimed, but rather a modified SEB. Thus, this language was selected to refer to the position in the modified

SEB compared to the corresponding location in natural type SEB. However, since this understanding appears to be evident, the language is unnecessary and has been removed from the claims. Reconsideration and withdrawal of this rejection are respectfully requested.

In summary, Applicants respectfully submit that the present claims fully satisfy the requirements of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of these rejections are respectfully requested.

Issues Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 1, 3, 5 and 9-13 under 35 U.S.C. § 112, second paragraph, for the reasons recited at page 7 of the outstanding Office Action. Applicants respectfully traverse these rejections.

First, the Examiner has rejected the use of the term "derivative thereof" in the claims. The Examiner questions what constitutes a derivative and how much of the modified SEB's original structure is to be retained. As discussed above, the derivative language refers to the amino acid being substituted and not to the entire modified SEB. Regardless, Applicants have removed this language from the claims.

Second, the Examiner has rejected claim 13, pointing out that it depends from a cancelled claim. Applicants have amended claim 13 to avoid this issue and to depend only upon pending

claims.

Third, the Examiner has rejected claim 1 for reciting "natural type SEB", "SEB" and "recombinant wild-type SEB". To remove the conflict between the "natural type SEB" and "recombinant wild-type SEB", Applicants have amended "recombinant wild-type SEB" to recite "recombinant natural type SEB." These two SEB's are considered in the art to be interchangeable nomenclature for the same molecule. However, Applicants have not altered the recitation of the "SEB" when used by itself and do not believe that this term should be included in this rejection. The "SEB" is the topic of the present invention and thus not only differs from natural type SEB in structure, but also function. Accordingly, it should not share the same designation.

Fourth, the Examiner has rejected claims 1, 3, 5 and 9 asserting that there is insufficient antecedent basis for the limitation "natural type SEB". The Examiner has suggested an amendment to insert the word "the" prior to this limitation. Applicants have adopted this suggested language.

In summary, Applicants respectfully submit that the present claims fully satisfy the requirements of 35 U.S.C. § 112, second paragraph. Reconsideration and withdrawal of these rejections are respectfully requested.

Issues Under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1, 3, 5 and 9-13 under 35

U.S.C. § 102(b) as being anticipated by Kappler et al., WO 93/14634 (hereinafter referred to as Kappler '634). Applicants respectfully traverse.

Kappler '634 discloses the preparation of modified (mutations)/derivatives of SEB. In particular, Kappler '634 discloses a technique for reducing toxicity of SEB when administered into a living body. However, Kappler '634 fails to suggest or disclose that such modifications of SEB with reduced toxicity could be used for prophylaxis/remedy of autoimmune diseases such as rheumatoid arthritis, ulcerative colitis, etc. with high safety.

The description of Kappler '634 on pages 12-14 and 17 discloses the knowledge at the time when that application was filed. For example, Kappler '634 discloses that the modifications of SEB interact with the  $V\beta$  elements of T cell receptors in a way which leads to modifications in the way T cells respond to a superantigen, including deletion or inactivation/desensitization of T cells as well as enhancing T cells. Specifically, Kappler '634 discloses that "The molecules of this invention can function in this manner, i.e., by leading to deletion or inactivation/desensitization of at least one or more subpopulations of T cells which present a particular  $V\beta$  element" (page 14, lines 20-24).

Kappler '634 differs from the present invention which recites in the claims the limitation "without inducing

elimination of T cells having specific V $\beta$  component, the elimination being normally induced by natural type SEB or recombinant natural type SEB" (see claim 1 of the present invention).

Moreover, it has been shown in Examples 6 and 7 that the SEB modifications of the present invention are efficacious by oral administration. Prior to the present invention, orally administered modified SEBs have never been disclosed nor suggested in the prior art. This was due to the fact that SEB might be a cause of certain diseases such as food poisoning.

Additionally, Applicants respectfully submit that Kappler '634 fails to suggest or disclose the SEB modifications as described in limitations a), b) and c) of claim 1. Accordingly, this rejection is improper and should be withdrawn. Reconsideration is requested.

In view of the above, Applicants respectfully submit that the present claims define subject matter which is patentable over the cited art and fully satisfies the requirements of 35 U.S.C. § 112, first and second paragraph. Accordingly, the Examiner is respectfully requested to withdraw all outstanding rejections and allow the currently pending claims.

Pursuant to the provisions of 37 C.F.R. §§ 1.17 and 1.136(a), the Applicants hereby petition for an extension of three (3) months to January 9, 2005 in which to file a reply to the Office Action. The required fee of \$1,020.00 has been paid with the

concurrent filing of a Notice of Appeal.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Craig A. McRobbie (Reg. No. 42,874) at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By 

Marc S. Weiner, #32,181

Craig A. McRobbie, # 42,874

MSW/CAM/mmi  
0020-4736P

P.O. Box 747  
Falls Church, VA 22040-0747  
(703) 205-8000